410.016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	S.G. Rimell
E. THIBAULT et al	:	
Serial No.: 09/308,195	:	Group: 2175
Filed: May 12, 1999	:	
For: METHOD...PROCESS	:	

475 Park Avenue South
New York, N.Y. 10016
October 19, 2004

APPENDIX

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The claims on appeal are as follows:

Claim 2

The process according to claim 15, wherein validation of the final certification is conditional on input of a validation password with a computer.

Claim 3

The process according to claim 15, implemented in a data processing system, wherein with each validation step is associated with at least one screen page

PO: a screen page which provides the process operator

PEI: screen page corresponding to a stage of a process number

EP: title

EA: retrospective analysis screen page

EC: certification screen page

EI: anomalies screen page

which can be accessed on a display means of at least one computer workstation connected to said data processing system.

Claim 4

The process according to claim 3, wherein each screen page comprises coded identification field for a patient which matches a batch of samples subjected to the standard operating procedure.

Claim 5

The process according to claim 15 wherein exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) corresponding to these stages.

Claim 6

The process according to claim 15 implemented in a preparation laboratory receiving therapeutic kits from at least one operational entity (EX), wherein it further comprises stages for monitoring the transfer of these kits.

Claim 7

The process according to claim 15 implemented in a preparation laboratory which deals with a cytapheresis service, wherein it further comprises stages for monitoring the receipt of cytapheresis pouches.

Claim 8

The process according to claim 15 implemented in a preparation laboratory which deals with a control laboratory, wherein it further comprises stages for processing results of control tests carried out on each batch of samples.

Claim 10

A system according to claim 16, implemented in a preparation laboratory, designed to execute management tasks of a preparation laboratory number n within this laboratory.

Claim 11

A system according to claim 16, wherein it is connected to a communications network to exchange data with other entities selected from the group consisting of: treatment centers number n, cytapheresis services number n, collection centers number n and, bacteriological testing laboratories involved in a therapeutic process.

Claim 12

Application of the process and of an information processing system used for quality management according to claim 15 to cell therapy protocols.

Claim 13

Application of the process and of an information processing system used for quality management according to claim 15 to gene therapy protocols.

Claim 14

Application of the process and of a quality management system according to claim 15, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge.

Claim 15

A method for processing information used for quality management in a therapeutic process involving several entities, including an operational entity and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages, ~~it~~ comprising, for each batch of samples taken from a given patient:

- after each functional stage, a stage of sequential and conditional validation of said functional stage, passing from one validation stage to a following validation stage being conditional on results of processing data collected during this validation stage and on a full completion by an operator of operational instructions within a screen page associated with said functional stage, said screen page being closed responsively to a closing order only if all said instructions have been carried out,

-a stage of processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being in particular indicative of operators and of the process state of progress, in order to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation, and wherein an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during said processing stage and

a stage for inputting post-reinjection follow-up information and forwarding said information to said operational entity.

Claim 16 (previously presented)

System for processing information used for quality management in a therapeutic process involving several entities, including an operational entity, and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages,

comprising, for each batch of samples taken from a given patient:

for each functional stage, a means of sequential and conditional validation of said stage, passing from one validation stage to a following validation stage being conditional

on results of processing of data collected during this validation stage and on a full completion by an operation of-cooperational instructions within a screen page associated with said functional stage, said screen page being closed responsively to a closing order only if all said instructions have been carried out,

means for processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being indicative in particular of operators and of the process state of progress, in order to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation,

means for providing an alarm icon for prompting an operator to consult a screen page listing anomalies detected during said processing stage, and

means for inputting post-reinjection follow-up information and forwarding said information to said operational entity.